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VIA E-MAIL

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Re: Response to AHETF's Petition to Cancel Ragan & Massey's Technical Glufosinate (EPA Reg. No. 84009-34)

Dear Mr. Cole and Ms. Sleasman:

This letter constitutes the Response of Ragan & Massey, Inc. ("RM") to the Petition filed by the Agricultural Handler Exposure Task Force ("AHETF") requesting that the U.S. Environmental Protection Agency ("EPA") require RM to cite and offer to pay for certain data submitted by AHETF to maintain its registration for RM Glufosinate-Ammonium Technical issued by EPA on February 11, 2020 (Reg. No. 84840-3), and cancel that registration if RM fails to do so.

The essence of the AHETF's argument is that EPA's decision to grant RM's technical glufosinate registration was wrong. In making this argument, AHETF blurs the important distinction between an application that relies on the cite-all method of data citation, and an application that relies on the selective method of data reliance used by RM. As EPA has explained, a selective method application may cite only the "minimum" set of data, and need not cite additional studies that also may satisfy the same data requirements addressed by data the applicant selectively cited. Indeed, that is one of the primary purposes of the selective method. As such, the AHETF's argument that EPA erred in failing to require RM to cite AHETF data to satisfy occupational exposure data requirements – in addition to the other data RM selectively cited to satisfy those same requirements – is without merit and should be rejected. In addition, AHETF's argument also overlooks the limited nature of RM's registration and seeks to require RM to cite data relevant to uses that RM did not register. Accordingly, AHETF's petition should be denied.

Background

1. Legal Background

As implemented by EPA, FIFRA and its regulations require that an applicant seeking a pesticide registration satisfy the applicable data requirements that EPA has imposed. *See, e.g.*, 40 C.F.R. § 152.50(f) ("An applicant must submit materials to demonstrate that he has complied with FIFRA sec. 3(c)(1)(F) and subpart E of this part with respect to *satisfaction of data requirements* …") (emphasis added). A "follow-on" or generic registrant seeking to satisfy EPA's data requirements has two options for doing so: the cite-all method (40 C.F.R. § 152.86) and the selective method (40 C.F.R. § 152.90).

As EPA explained in the Preamble to the Final Rule promulgating its data reliance regulations, the selective method, in contrast to the cite-all method, enables an applicant to cite and offer to pay compensation for the "minimum data set" required to support registration of the applicant's product. 49 Fed. Reg. 30884, 30893 (Aug. 1, 1984). Under the selective method, the applicant first must list each data (or "guideline") requirement applicable to its proposed product in its data matrix. 40 C.F.R. § 152.90(a). The applicant then must demonstrate compliance with each listed data requirement through one of several methods, such as citation to a specific study or studies that satisfy the requirement (the "straight" selective method), or citation to all data pertinent to the requirement (the "cite-all option" under the selective method). *Id*. § 152.90(b).

EPA created the selective method in response to the decision in *NACA v. EPA*, 554 F. Supp. 1209 (D.D.C. 1983), which rejected EPA's prior interpretation of FIFRA § 3(c)(1)(F) as requiring a follow-on applicant to cite *all* "data which the Agency might review or use in deciding whether to register his product, *i.e.*, all relevant data in the Agency's files." 49 Fed. Reg. at 30885. EPA explained that "[a]fter reviewing the statute in detail in light of the *NACA* decision, the Agency concluded … that there is an *important distinction* in the statute between (1) EPA review under FIFRA § 3(c)(1)([F]) to determine whether the applicant has satisfied the requirements that specify how an application must be supported by submission or citation for data, and (2) EPA review of data to determine whether to approve a properly supported application on risk/benefit grounds." *Id.* at 30887 (emphasis added); *see also id.* n.3 (noting that the *NACA* court rejected EPA's previous interpretation that these two functions are "indistinguishable"). Thus, the Agency must engage in "two separate data review functions" in determining whether a proposed pesticide meets the registration standards in FIFRA § 3(c)(5). *Id*. at 30887-88. The first data review requires the Agency to determine whether the applicant has cited or submitted sufficient data to satisfy applicable data requirements to meet the standard in § 3(c)(5)(B). *Id*. at 30887. The second data review function requires EPA to consider any and all available data to determine whether the pesticide meets the risk/benefit criteria set forth in § 3(c)(5)(C) and (D). *Id*. at 30887-88, 30902. Critically, whereas EPA's consideration of data in the first review is governed by FIFRA's data compensation provisions, a broader universe of data it may consider to make the risk/benefit determinations required by subparagraphs (C) and (D) is not. *Id.*

EPA has repeatedly affirmed and applied this "important distinction" in regulatory decisions, letters, and other Agency pronouncements. For example, in its April 11, 2000 decision on a petition to deny a registration, the Agency explained:

> Although EPA necessarily takes into account all relevant information available to the Agency when evaluating an application for a particular use of a pesticide, it does not follow that an applicant must offer to pay compensation for all such data. There is an ***important distinction*** between EPA review of data that an applicant must submit or cite in support of an application

> in order to satisfy the requirements of FIFRA section 3(c)(1)(F), and EPA review of data for other scientific purposes ….

Decision at 3-4 (citing 49 Fed. Reg. at 30888) (emphasis added) (Exh. 1). Similarly, in its March 21, 2011 decision rejecting a petition submitted by Bayer to deny or cancel registration held by Ensystex, EPA explained:

> Bayer also asserts that because Ensystex IV's application does not cite to or contain all the data necessary for registration, EPA does not have available to it data necessary to make the required [no unreasonable risk] finding[s] under FIFRA. Not so. *It is well established that for purposes of making its risk/benefit determination, EPA is not limited to data cited or provided by the applicant.*

Decision at 9 n.5 (citing 49 Fed. Reg. at 30888) (emphasis added) (Exh. 2).

EPA's statutory reading that its consideration of data in making risk assessments concerning a pesticide does not, in itself, render the data a "data requirement" and subject to FIFRA's compensation provisions has also been affirmed in Agency letters to the industry. One example is EPA's June 19, 2001 letter responding to an inquiry from the Spray Drift Task Force ("SDTF") as to whether EPA's use of SDTF data in risk assessments for particular pesticides renders those data compensable for registrants of those pesticides. EPA advised:

> [A]n applicant is obligated to submit or cite all data necessary to satisfy EPA data requirements; applicants are not required to submit or cite all data that EPA may evaluate for the purpose of determining whether the pesticide satisfies the FIFRA unreasonable adverse effects standard or the FFDCA section 408 safety standard…. Accordingly, the critical inquiry in determining whether a given data submitter such as the SDTF is entitled to an offer of compensation is whether an applicant must rely on the submitter's data to satisfy Agency *data requirements*.

Decision at 1-2 (emphasis added) (Exh. 3).

Another example is EPA's February 11, 2014 letter responding to an inquiry from the Generic Residential Exposure Task Force ("GRETF"), which was formed to develop data required by a DCI concerning pyrethroids, in lieu of joining the existing Residential Exposure Joint Venture ("REJV"). The GRETF requested confirmation that EPA's use of REJV data in risk assessments for individual pyrethroids while GRETF's data were being generated would not trigger compensation obligations. EPA agreed, explaining:

> You are correct that EPA's consideration of data in making a registration review or registration determination does not by itself compel submission or citation of data. EPA must first require those data…. [I]f GRETF members choose to satisfy registration review data needs for pyrethroids through submission of their own data, and those data meet EPA requirements, GRETF is not required to cite other data submitted, including data generated by the … [REJV], even if EPA uses the REJV data in conducting its risk assessment.

Letter at 1 (emphasis added) (Exh. 4).

2. EPA's Registration of RM Glufosinate- Ammonium Technical

On or about January 20, 2019, RM submitted an application to EPA to register RM Glufosinate-Ammonium Technical. RM sought and obtained its registration using the selective method of data citation. *See* Exhibit 5 (RM selective data matrix). To satisfy occupational exposure

data requirements, RM selectively cited data in EPA's Pesticide Handler Exposure Database ("PHED"). *See id.* On February 11, 2020, EPA determined that RM had satisfied all data requirements applicable to the registration requested for RM Glufosinate-Ammonium Technical, and granted the registration. Exh. 6. The registration obtained by RM does not include the full range of uses registered by other registrants. Exh. 5. Rather, RM Glufosinate-Ammonium Technical is registered for use only in non-crop, residential and industrial areas. *Id*.

Argument

AHETF's contention in its Petition that RM is required to "submit or cite ***all*** data required" cannot be squared with the purpose and scope of the selective method of data citation used by RM. Pet. at 3 (emphasis added). While an applicant using the cite-all method may cite all data previously submitted to EPA that satisfies the applicable data requirements, RM used the narrower selective method. In contrast to the cite-all method, under the selective method, RM need only cite *sufficient* – not *all* – data to satisfy each of EPA's data requirements for the registration sought. 40 C.F.R. § 152.90(b). The selective method permits RM to pick and choose among potentially duplicative data or data sets and cite only the "minimum data set" required to support registration of its product. 49 Fed. Reg. at 30893. In other words, if one or more studies previously submitted to EPA satisfies a particular data requirement, an applicant using the selective method need only cite one such study. *Id.*; 40 C.F.R. § 152.90(b). As EPA explained, use of "[t]he selective method … reduce[s] the potential for having to pay compensation for several similar studies satisfying the same data requirement, since the applicant can generally demonstrate compliance by citing a single specific valid study for each individual data requirement." *Id*. at 30894. EPA is responsible for determining whether the "minimum data set" cited in an application submitted under the selective method is sufficient to satisfy each of the applicable requirements, and it must make that determination prior to granting a registration. 49 Fed. Reg. at 30893; *see id.* at 30898 (explaining that EPA must review both the applicant's list of data requirements and the data cited to ensure all requirements are satisfied).

AHETF does not claim that RM omitted applicable data requirements in its data matrix. Instead, AHETF takes issue with the fact that RM cited PHED data to satisfy occupational exposure requirements, but did not cite AHETF's data that it contends are relevant to those same requirements. With little explanation, AHETF asserts that EPA's conclusion that RM's application to register RM Glufosinate-Ammonium Technical satisfied the applicable data requirements was in error. AHETF seems to contend that, because its data were submitted more recently that the PHED data, RM should be required to cite them. But the mere existence of AHETF's data set does not mean that RM is required to cite its – or "all" – data that may satisfy occupational exposure data requirements. Under the selective method, RM need only cite data sufficient to satisfy the applicable requirements; it is not required to cite "all" data in EPA's files that may address those same requirements. 49 Fed. Reg. at 30887; *see* 40 C.F.R. § 152.90(b). EPA, of course, is aware that AHETF also submitted data that may be relevant to occupational exposure requirements. Had EPA believed citation of PHED data was insufficient – and that citation of AHETF data was required – it could not have issued the registration for RM Glufosinate-Ammonium Technical.

In addition to misunderstanding the scope of a selective method application, AHETF also misunderstands the scope of RM's registration for RM Glufosinate-Ammonium Technical. As noted, RM Glufosinate-Ammonium Technical is registered for use only in non-crop, residential and industrial areas. Exh. 6. It is not, for example, registered for use on cotton or other crops, on turf, or in greenhouses and orchards. However, the list of data AHETF requests that EPA require RM to cite includes data relevant to these uses that are not permitted by the registration and label for RM

Glufosinate-Ammonium Technical.[1] AHETF makes no effort to explain the basis for these (or any other) items in the data list attached to its Petition.

In short, AHETF simply asserts that EPA's decision is wrong, but does not explain the basis for its contention that (1) each PHED data item RM cited to address occupational exposure data requirements is insufficient to satisfy the requirement, and (2) that each of the 35 items it believes RM should cite is relevant and should be required for RM's registration. Particularly under the selective method regulation, generalized or sweeping assertions such as those made by AHETF are insufficient. Instead, the selective method calls for separate analysis for each data requirement and for each item of data allegedly required to satisfy those requirements. *See* 40 C.F.R. §152.90(a)-(b). As the party petitioning EPA and contending that EPA's decision to grant the registration for RM Glufosinate-Ammonium Technical was in error, AHETF's Petition should have included such an explanation for each item of the PHED data cited by RM and each of the 35 data items that are the subject of its Petition. As reflected in EPA's decision to grant the registration for RM Glufosinate-Ammonium Technical, RM's citation of PHED data satisfies EPA's requirements related to occupational exposure and AHETF's Petition should be denied. However, if AHETF is given the opportunity to supplement its Petition with missing explanation and detail about the basis for its position concerning the alleged insufficiency of each item of PHED data cited by RM and each item of AHETF data it contends RM should cite, RM requests a fair opportunity to respond.

Sincerely,

Cristen S. Rose
James P. Rathvon

Attachments

cc: Rachel Holloman, EPA
Erik Kraft, EPA
Mackenzie S. Schoonmaker, Counsel for AHETF
Stephanie Schwarz, EPA
Manjula Unnikrishnan, EPA

[1] *See, e.g.*, MRID Nos. 46763702, 47212801, 47309201, 47309202, 47309203 and 4730903.

Exhibit 1

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

APR 11 2001

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RE: Petitions to Deny

Dear Mr. Weinberg and Ms. Szmuszkovicz:

On June 21, 1999, the Agency received FMC Corp.'s (FMC's) "Petition to Deny Applications of United Phosphorus Inc. (UPI) for Registrations of Pesticides Containing the Active Ingredient Permethrin." On September 16, 1999, the Agency received Zeneca Inc.'s (Zeneca's) "Petition to Deny Applications of UPI for Registration of Pesticides Containing Permethrin as the Active Ingredient." FMC's and Zeneca's petitions were filed pursuant to 40 C.F.R. §152.99, which permits original data submitters to seek denial or cancellation of the registration of a product where the applicant for that product has failed to satisfy a data requirement the petitioner has fulfilled. Because the claims in FMC's and Zeneca's petitions mirror one another, the Agency has considered these petitions jointly.

On May 27, 1999, UPI submitted applications to register Permethrin Technical, Tengard MUP, and Tengard SFR. All three products contain permethrin as the sole active ingredient. In support of its applications for registration, UPI was required to comply with the data submission provisions of FIFRA section 3(c)(1)(F) and 40 C.F.R. Part 152, Subpart E – Procedures to Ensure the Protection of Data Submitters' Rights. In general, Subpart E requires applicants either to submit data regarding the various chemical properties, environmental effects, and toxic effects of the their products, or to rely on data previously submitted to the Agency by prior applicants.

Initially, UPI elected to submit its own product chemistry studies and to rely on EPA's selective method, *see* 40 C.F.R. §152.90, to support its registration applications. Subsequently, UPI amended its applications and relied on 40 C.F.R. §152.95, commonly referred to as the selective cite-all method, to support its registration applications. In relying on the selective cite-all method, UPI cited to all of the studies in the Agency's files pertinent to all of the data requirements for its products.

In addition to the submission of data or citation to data, UPI was required to offer to pay compensation to those persons who previously submitted data to the Agency upon which UPI's applications relied. UPI sent offer to pay letters dated May 26, 1999, to FMC and Zeneca. UPI's offer to pay was limited to FMC's and Zeneca's studies listed on UPI's selective-cite data matrices for Permethrin Technical, Tengard MUP, and Tengard SFR to the extent required by FIFRA section 3(c)(1)(F). When UPI amended its applications to rely on the selective cite-all method, its May 26, 1999, offer to pay letters to FMC and Zeneca were superseded by offer to pay letters dated January 11, 2000, and January 28, 2000. In the January 11, 2000, letters, UPI offered to pay compensation "with regard to UPI's Permethrin Technical and Tengard MUP applications, to the extent required by FIFRA §3(c)(1)(D) [sic] of [FIFRA] for the specific data requirements identified in the attached appendix." UPI split its originally-proposed end-use label for Tengard SFR into two separate labels–Tengard SFR and Tengard HG. In letters to Zeneca and FMC dated January 28, 2000, UPI offered to pay compensation with regard to these end-use products for the specific data requirements identified in the appendix attached to the letters. Finally, UPI submitted to the Agency a general offer to pay statement, as required by 40 C.F.R. §152.95(a), for any previously submitted data that may satisfy the guidelines listed in UPI's data matrix.

In a letter dated February 8, 2000, Zeneca "note[d] that the list provided by UPI [in its subsequent offer to pay letter] does not address several guidelines" satisfied by Zeneca and others, including "guideline numbers 122-1, 165-1, 165-2, 165-5, and seventeen additional ecotoxicology and spray drift submissions by members of the [Pyrethroid Working Group (PWG)]." However, as described below, the Agency has determined that UPI has satisfied the data requirements for registration.

The Agency's data requirements for registration are codified at 40 C.F.R. Part 158. In determining registration data requirements to satisfy FIFRA section 3(c)(1)(F), applicants are instructed to "[s]elect the general use pattern(s) that best covers the use pattern(s) specified on the pesticide product label" and to "[p]roceed down the appropriate general use pattern column in the [Data Requirement] table and note which tests . . . are required ("R"), conditionally required ("CR") or usually not required ("--- ")." 40 C.F.R. §158.100(b) and (c). Thus, under EPA regulations, data requirements are based on use patterns proposed by the applicant and not on the use patterns of existing registrants.

UPI's proposed labels are limited to non-food/feed, indoor/outdoor termiticide/insecticide use patterns. Guideline numbers 165-1, 165-2, and 165-5 are not listed as required data under 40 C.F.R. §158.290 for UPI's proposed use patterns. Guideline number 122-1 is required under 40 C.F.R. §158.540, but only if the pesticide is to be used in forests or natural grasslands or when other stipulated conditions are met. *See* 40 C.F.R. §158.540(b)(2). UPI's proposed uses do not meet these conditions. Similarly, because UPI's proposed labels are limited to non-crop uses and are not intended for major uses (e.g., cotton, corn soybeans, forests, etc.), UPI is not required to cite to the additional ecotoxicology and spray drift submissions by PWG members. UPI cited to all of the studies in the Agency's files pertinent to the following wildlife and aquatic organisms data guideline numbers: 71-1, 71-2, 71-4, 72-1, 72-2, 72-3, and 72-4. Although other aquatic and wildlife organisms data may be conditionally required, the potential exposure from UPI's intended use patterns do not warrant requiring such upper-tiered, life-cycle and field testing studies. *See* 40 C.F.R. § 158.490, notes 2, 6, and 8. Furthermore, UPI is not required to submit or cite to spray drift studies because UPI's proposed labels are not intended for aerial applications or broad area ground applications. *See* 40 C.F.R. §158.440(a), note (1).

All of the other claims[1] except for one in FMC's and Zeneca's petitions were rendered moot by UPI's amended applications and citation of all studies in the Agency's files pertinent to all of the data requirements for UPI's pesticide products. The only remaining issue for consideration is whether UPI must offer to pay compensation for or generate aggregate exposure data necessary for permethrin tolerance reassessment where permethrin is registered for both food and non-food uses but UPI's proposed uses are limited to non-food/feed uses and indoor/outdoor termiticide/insecticide uses. This is an issue of first impression before the Agency.

The Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), requires EPA to reassess all existing tolerances by making a safety determination consistent with section 408(b)(2). FFDCA §408(a). A tolerance is "safe" if there is "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all other exposures for which there is reliable information." FFDCA §408(b)(2)(A)(ii). When assessing the safety of pesticide chemical residues on food, the Agency must consider "available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances . . . ." FFDCA §408(b)(2)(D). Thus, in reviewing tolerance actions, the FFDCA requires EPA to assess aggregate exposure from multiple routes of exposure, including drinking water and other non-occupational uses. Congress imported this requirement into FIFRA by amending section 2(bb). Accordingly, in making unreasonable adverse effects determinations pursuant to FIFRA section 3(c)(5)(D), the Agency must consider whether there is "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard" under FFDCA section 408. FIFRA §§2(bb). Furthermore, the Agency stated in PR Notice 97-1 that it "intends to apply a similar standard to actions involving non-food use pesticides that may pose significant non-dietary risks to infants and children." EPA, Office of Pesticide Programs, Pesticide Registration (PR) Notice 97-1 (Jan. 31, 1997).

According to Zeneca, the FQPA's "new requirement to assess aggregate risk has eliminated much of the traditional distinction between requirements for food uses and non-food uses of pesticides that, like permethrin, are registered for both types of uses." Zeneca Petition at 13. Zeneca contends that "under the FQPA, the registrability of non-food uses of pesticides that are also registered for food uses is dependent in part upon data submitted to support the granting of a tolerance or exemption from the requirement of a tolerance." *Id.* Likewise, FMC maintains that "the continued authorization of non-food uses for those pesticides used for both food and non-food purposes rests, in substantial part, on data supporting tolerances and tolerance decisions." FMC Petition at 5. FFDCA section 408(i)(1) provides that data submitted to the Agency "in support of a tolerance or an exemption from a tolerance shall be entitled . . . to exclusive use and data compensation to the same extent" provided by FIFRA. Therefore, both FMC and Zeneca assert that UPI must offer to share in the costs of generating the data necessary for permethrin tolerance reassessment under the FQPA or generate the data itself.

Although EPA necessarily takes into account all relevant information available to the Agency when evaluating an application for a particular use of a pesticide, it does not follow that the

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[1]FMC's petition raised three claims: (1) UPI failed to properly document data gaps; (2) UPI failed to submit offers to pay compensation to the appropriate data submitters; and (3) UPI failed to include all required studies in its data matrices. Zeneca's petition raised two fundamental claims: (1) UPI failed to satisfy data requirements that have been satisfied by Zeneca and others; and (2) UPI failed to demonstrate how it will meet outstanding data requirements for registration under FIFRA and for tolerance reassessment under the FQPA.

applicant must offer to pay compensation for all such data. As discussed above, data requirements are based on use patterns proposed by the applicant and not on the use patterns of existing registrants. *See* 40 C.F.R. Part 158. There is an important distinction between EPA review of data that an applicant must submit or cite in support of an application in order to satisfy the requirements of FIFRA section 3(c)(1)(F), and EPA review of data for other scientific purposes: "In the latter review, EPA may consider any relevant data without regard to who submitted the data, for what purpose, or when the data were submitted. In contrast, very specific limitations apply to the Agency's consideration of data in the first review." *See* EPA, Pesticide Registration and Classification Procedures; Procedures to Ensure Protection of Data Submitters' Rights, 49 Fed. Reg. 30884, 30888 (1984) (codified at 40 C.F.R. Parts 152 and 162).

Accordingly, the Agency may use data for whatever scientific purposes it deems necessary, including tolerance reassessment, provided that the Agency has adequately ensured the economic protections intended by FIFRA section 3(c)(1)(F). It is EPA's position that the current regulations continue to safeguard the economic protections provided by FIFRA section 3(c)(1)(F) by ensuring that each registrant bears responsibility for submitting or citing to data for the specific uses for which the product is intended. As the Agency explained in the 1984,

> FIFRA section 3(c)(1)(F)[2] clearly applies only to information required to be submitted with the application, not information used for any other purpose under FIFRA. The Agency may, and does, consider data for various scientific purposes--to determine risk/benefit consequences of use, to determine whether restrictions on use are necessary, to determine proper labeling for products, to determine whether to cancel or suspend a pesticide. In all these cases, the Agency uses data to arrive at its decision. But section 3(c)(1)(F) applies to Agency consideration of data for one purpose only--the Agency's determination under section 3(c)(5)(B) that "material required to be submitted [by section (3)(c)(1)] complies with the requirements of the Act." Having determined that the economic protections intended by section 3(c)(1)(F) have been adequately ensured, the Agency may subsequently use the data for whatever scientific purposes it deems necessary, by itself or together with other available information. It is the Agency's opinion that such use is not governed by section 3(c)(1)(F), and that consideration of any data for purposes other than sufficiency of an application under section 3(c)(5)(B) does not trigger the application of the exclusive use or compensation provisions of section 3(c)(1)(F) to that data.

49 Fed. Reg. at 30902.

Moreover, such a distinction is buttressed by the District Court for the District of Columbia's decision in *National Agricultural Chemicals Association v. U.S. Environmental Protection Agency*, 554 F. Supp. 1209 (D.D.C. 1983) (hereinafter "*NACA*"). In that case, the court rejected EPA's interpretation of FIFRA contained in the Agency's 1979 cite-all regulations, and held the 1979 regulations invalid insofar as they required an applicant to cite every study in the Agency's files relevant to the applicant's product. The district court enjoined EPA from requiring applicants to submit or cite more data than needed to meet the "statutory criteria for registration."

This distinction is further supported by congressional intent. Congress intended for the

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[2] After this statement was made in 1984, FIFRA was subsequently amended. Consequently, the provisions that appeared in section 3(c)(1)(D) in 1984 now appear in section 3(c)(1)(F). Therefore, 3(c)(1)(F) has been substituted for 3(c)(1)(D) throughout this quotation.

Agency to review data other than those submitted by applicants, as evidenced in several provisions of FIFRA. Sections 3(c)(5) and (7) require the Agency to determine that either the product and its uses will not cause unreasonable adverse effects on the environment, or that use of the product will not significantly increase the risk of unreasonable adverse effects on the environment. Under FIFRA section 2(bb), the term "unreasonable adverse effects on the environment" means:

> (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a).

This definition "clearly contemplates that the Agency will examine information beyond that which applicants are required to provide." 49 Fed. Reg. at 30888. Moreover, FIFRA section 3(c)(2)(A) requires that the Administrator make available to the public after registration "the data called for in the registration statement together with such other scientific information as the Administrator deems relevant to the Administrator's decision." "Other scientific information," as the Agency has pointed out before, "clearly refers to information distinct from that submitted by the applicant." 49 Fed. Reg. at 30888.

In sum, requiring UPI to share in the costs of generating the data necessary for permethrin use patterns that have not been proposed by UPI would run contrary to current Agency regulations at 40 C.F.R. Part 158 and, as supported by *NACA* and congressional intent, is not mandated by FIFRA section 3(c)(1)(F). In passing FFDCA section 408 and amending FIFRA section 2(bb), the Agency does not believe that Congress intended to compel sweeping changes in the data compensation scheme that, in large measure, would render the current data tables in Part 158 meaningless and increase by considerable–in some instances geometric–proportions the obligations of applicants and EPA in satisfying FIFRA's data submission and application review requirements. UPI submitted or cited data in support of its applications based on its proposed use patterns. The Agency has determined that UPI's submissions satisfy the requirements of 40 C.F.R. Part 158 and that the economic protections intended by FIFRA section 3(c)(1)(F) have been adequately ensured. As discussed above, the Agency may subsequently use data, by itself or together with other available information, for whatever scientific purposes it deems necessary, including both adverse effects determinations and tolerance decisions. Therefore, FMC's and Zeneca's petitions to deny are denied.

Sincerely,

James J. Jones, Director
Registration Division

cc: James C. Wright, Esq.
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Exhibit 2

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

CERTIFIED MAIL

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MAR 2 1 2011

James P. Rathvon
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500 Eighth Street, NW
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Re: Petition of Bayer CropScience, LP to Cancel Imidacloprid Registrations and Deny Imidacloprid Applications of Ensystex III, Inc. and Ensystex IV, Inc.

Dear Mr. Sachs and Mr. Rathvon:

This letter constitutes the response of the Environmental Protection Agency (EPA or Agency) to a petition filed by Bayer CropScience, LP (Bayer) dated September 8, 2009, to cancel all technical and end-use registrations for imidacloprid held by Ensystex III, Inc. and Ensystex IV, Inc. (together, Ensystex), and to deny any pending Ensystex applications for additional imidacloprid end-use products. EPA is in receipt of the following submissions:

1. Petition of Bayer to Cancel Imidacloprid Registrations and Deny Imidacloprid Applications of Ensystex III, Inc. and Ensystex IV, Inc., September 8, 2009.

2. Response to Bayer's Petition to Cancel Imidacloprid Registrations and Deny Imidacloprid Applications of Ensystex III, Inc. and Ensystex IV, Inc., November 9, 2009.

3. Reply in Support of Bayer's Petition to Cancel Imidacloprid Registrations and Deny Imidacloprid Applications of Ensystex III, Inc. and Ensystex IV, Inc., November 20, 2009.

4. Surreply of Ensystex III, Inc. and Ensystex IV, Inc., February 2, 2010.

5. Reply in Support of Bayer's Petition to Cancel Imidacloprid Registrations and Deny Imidacloprid Applications of Ensystex III, Inc. and Ensystex IV, Inc., July 15, 2010.

Background

On October 16, 2006, EPA issued a technical imidacloprid registration for "ENS-101" (EPA Reg. No. 82957-1) to Ensystex III, Inc. (Ensystex III). On January 31, 2007, EPA issued a second technical imidacloprid registration to Ensystex III "ENS-010A" (EPA Reg. No. 82957-4). In addition, EPA issued registrations to Ensystex III for two end-use product containing imidacloprid as the active ingredient:

(1) "Prothor WP" (EPA Reg. No. 82957-2), approved on February 12, 2007; and

(2) "Turfthor WP" (EPA Reg. No. 82957-3), approved on November 2, 2006.

In connection with the applications for these registrations, it is undisputed that Ensystex III submitted an "offer to pay" dated October 24, 2006. Specifically, the letter provides that Ensystex III's application uses the selective method of support as well as the "cite-all within selective method" for particular guideline studies.

Subsequently, EPA issued several imidacloprid end-use product registrations to Ensystex IV, Inc. (Ensystex IV):

(1) "Bithor SC GC" (EPA Reg. No. 83923-1), approved on February 12, 2007;

(2) "Bithor SC" (EPA Reg. No. 83923-2), approved on February 12, 2007;

(3) "Prothor SC 0.5" (EPA Reg. No. 83923-3), approved on March 6, 2007;

(4) "Prothor SC 2" (EPA Reg. No. 83923-4), approved on March 6, 2007; and

(5) "Turfthor 2F" (EPA Reg. No. 83923-5), approved on August 21, 2007.

It is undisputed that Ensystex IV submitted an "offer to pay" dated October 24, 2006 for Prothor SC 0.5, Prothor SC 2, Bithor SC, and Bithor SC GC. The letter informed Bayer that Ensystex IV intended to use the cite-all under selective method of data support to satisfy acute toxicity and efficacy data requirements only.

In addition, EPA issued two imidacloprid end-use product registrations to Ensystex IV on August 8, 2008:

(1) "Turfthor 2.5G" (EPA Reg. No. 83923-9); and

(2) "Turfthor 0.5G" (EPA Reg. No. 83923-10).

Again, it is undisputed that Ensystex IV submitted an "offer to pay" to Bayer dated April 11, 2008 in connection with these end-use products. The letter informed Bayer that Ensystex IV intended to use the cite-all under selective method of data support to satisfy acute toxicity data requirements only. Finally, Ensystex IV also submitted an "offer to pay" to Bayer dated June 11, 2008 for two end-use products identified as "Bithor G" and "Bithor G GC." The letter informed Bayer that Ensystex IV intended to use the cite-all under selective method of data support to satisfy acute toxicity and efficacy data requirements only.

The substance of Bayer's petition, however, has to do with data requirements for which Ensystex III has not made a valid offer to pay. Specifically, Bayer asserts that its petition is "based upon the fact that Ensystex has not offered to compensate Bayer for the use of at least 33 items of imidacloprid data that were prepared and submitted to EPA by Bayer, and that are necessary to fulfill ecological effects, toxicology and environmental fate data requirements pertinent to Ensystex's registrations for imidacloprid."[1] Petition at 2.

Timeliness

The regulatory procedures governing petitions by an original data submitter to deny or cancel a registration are found at 40 CFR § 152.99. Section 152.99(a)(1) applies where an applicant has offered to pay compensation to the original submitter of a study. Section 152.99(a)(2) applies where no offer to pay has been made. Bayer's petition is explicitly made pursuant to section 152.99(a)(2); namely, that Ensystex III and Ensystex IV failed to make an offer to pay to Bayer for required data, and that Ensystex III and Ensystex IV failed to otherwise satisfy those data requirements. Petition at 4. Petitions filed pursuant to section 152.99(a)(2) "must be filed within one year after the Agency makes public the issuance of the registration." 40 CFR § 152.99(b)(1).

Bayer argues that its petition is timely because EPA first publicized the issuance of the registration of Ensystex IV's Turfthor 2.5 G and Turfthor 0.5G end-use product through its Pesticide Product Information System (PPIS) on September 8, 2008. In addition, the one year limitations period had not yet begun to run with respect to "Bithor G" and "Bithor G GC" because those registrations appeared to still be pending at the time Bayer petitioned the Agency to deny those applications. However, Bayer offers no argument as to the timeliness of its petition with respect to the remaining Ensystex III or Ensystex IV registrations.

EPA agrees that the petition is timely with respect to Bayer's challenge to Ensystex IV's "Turfthor 2.5 G" and "Turfthor 0.5G" end-use product registrations as well as the "Bithor G" and "Bithor G GC" applications. However, it is clearly untimely with respect to registrations granted and made public prior to September 8, 2008. Accordingly, with respect to Ensystex III and its technical registrations, ENS-101 and ENS-010A, as well as its Prothor WP and Turfthor WP end-use registrations, Bayer's petition is **DENIED** as untimely. In addition, with respect to Ensystex IV and its Bithor SC GC, Bithor SC, Prothor SC 0.5, Prothor SC 2, and Turfthor 2F, Bayer's petition is **DENIED** as untimely.

Formulators' Exemption

With respect to the registrations that remain at issue (Ensystex IV's "Turfthor 2.5 G" and "Turfthor 0.5G" end-use product registrations and its "Bithor G" and "Bithor G GC" applications), Ensystex IV argues that its end-use products are formulated using registered technical imidacloprid purchased from Ensystex III. Accordingly, Ensystex IV argues that the remaining registrations qualify for the formulators' exemption.

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[1] Bayer has also asserted that it is entitled to petition EPA under the Administrative Procedures Act (APA), 5 U.S.C. § 555(b) and the Petition Clause of the First Amendment to the United States Constitution. Petition at 5. However, Bayer has only raised claims that are subject to the data compensation petition process in 40 CFR, subpart E—Procedures to Ensure Protection of Data Sumitters' Rights. Insomuch as Bayer has in fact submitted petitions under the APA and the Petition Clause of the First Amendment to the United States Constitution, it does not appear that there is any further relief EPA can or should grant pursuant to those authorities.

The formulators' exemption originates in section 3(c)(2)(D) of the Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA), which provides:

> No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application shall be required to –
>
> (i) submit or cite data pertaining to such purchased product, or
>
> (ii) offer to pay reasonable compensation otherwise required ... for the use of such data.

In addition, EPA has issued regulations governing the formulators' exemption at 40 CFR § 152.85.

Ensystex IV argues that since all 33 data items addressed in Bayer's petition pertain to Ensystex III's technical products, Ensystex IV has no obligation to cite or offer to pay for those data. Alternatively, Ensystex IV argues that 26 of the 33 data items included in Bayer's petition were originally submitted more than 15 years ago and are no longer eligible for compensation. With respect to the remaining data items, Ensystex IV further argues that none are required to support Ensystex III's technical registration, on which Enystex IV's end-use registrations are based.[2]

Bayer argues that the formulators' exemption does not excuse Ensystex IV from offering to pay for data that have not been satisfied by the technical product that it purchases. According to Bayer, the formulators' exemption cannot overcome database deficiencies in the technical product. In support of this proposition, Bayer relies on a 2003 data compensation decision in which EPA held that the formulators' exemption does not exempt a formulator from meeting data requirements applicable to use patterns that differ from those supported by the purchased registered pesticide from which the product is formulated. *See* EPA Petition Response: In re Petition of Chlorpropham Task Force to Cancel Registration of Dataplex, S.A., (November 4, 2003) (hereinafter "*Dataplex*").

In *Dataplex*, a company called Pin Nip, Inc. had previously registered technical chlorpropham. Subsequently, Dataplex S.A., a formulator proposing to utilize the Pin Nip technical as its source of active ingredient, applied for and was granted a registration for an end-use product, claiming it was similar to other registered products on the market and asserting that it was exempt from the requirements of submitting, or citing and paying compensation for, generic data to support the application for registration pursuant to the formulators' exemption because it would produce its product from a registered pesticide. Dataplex's end-use product, however, included certain use patterns in addition to those that were supported by the Pin Nip technical product registration. Because the Pin Nip technical product registration did not support those use patterns, EPA determined that the discrete data requirements pertaining to those uses were outside the scope of the formulators' exemption. In so doing, EPA concluded that reading its regulations to exempt products from all data requirements, regardless of differences between the uses and claims made for formulated products and the purchased manufacturing use product from which it is produced would be inconsistent with the purpose of the formulators' exemption and the data compensation scheme established in FIFRA. *Dataplex* at 5.

[2] Because Bayer's petition is being denied on other grounds, EPA does not reach Ensystex's alternative arguements.

In explaining that section 3(c)(2)(D)(i) only exempts formulators from data requirements "pertaining to [the] purchased product," EPA stated that "a formulator is exempt from data requirements only to the extent that those data requirements have been satisfied for the purchased pesticide product." *Id.* Bayer has seized upon this and other language to argue that *Dataplex* is not limited to situations where the technical registration was not registered for the uses on the end-use product (and, therefore, could not have satisfied the data requirements for those uses). Rather, Bayer asserts that *Dataplex* stands for the proposition that the formulators' exemption does not apply to any data deficiency, regardless of whether the technical or manufacturing use product is registered for the same uses as the reformulated product. In so doing, Bayer has taken this statement out of context and advocates an interpretation of *Dataplex* that is both overly broad and inconsistent with EPA regulations and the plain meaning of the statute.

Again, the issue in *Dataplex* was whether the formulators' exemption applied to data requirements for use patterns that were in addition to those for which the purchased technical product was registered. The statement in *Dataplex* that the "formulator is exempt from data requirements only to the extent that those data requirements have been satisfied for the purchased pesticide product" was made in the context of rejecting Dataplex's argument that it is of no consequence what uses a technical or manufacturing use product is registered for as long as the formulator uses a registered technical or manufacturing product to formulate a product that is similar to some other registered product. The question of whether Pin Nip had adequately satisfied the data requirements applicable to its technical registration was not at issue. Thus, EPA's statements in *Dataplex* with respect to satisfaction of data requirements were solely directed to the actual data requirements associated with uses for which the "purchased pesticide product" was registered (as opposed to a determination as to whether those requirements had been "satisfied" by the technical registrant).

Indeed, EPA's explanation in *Dataplex* clearly confines the discussion of satisfying data requirements to the determination that the formulators' exemption cannot exempt a formulator from data requirements related to uses not supported by the technical product. *See Dataplex* at 5, 6, & 7 ("Reading [the formulators' exemption] to exempt products from all data requirements, regardless of differences between the uses and claims made for formulated product and the purchased manufacturing use product from which it is produced would be inconsistent with [the formulators' exemption] and the data compensation scheme established ... [in] FIFRA"; "Thus, the formulator could not produce from the [Pin Nip Technical] an end use [sic] product for use patterns that are not fully supported by the [Pin Nip Technical] registration, unless the formulator submits or cites data to support the additional use patterns"; "Because the [Pin Nip Technical] registration does not support those use patterns, they are outside the scope of the formulators' exemption, and Dataplex is required to submit or cite data to support these use patterns"; Dataplex has not submitted or cited data to support use patterns...that are additional to those for which the [Pin Nip Technical] is registered").

Furthermore, as part of EPA's explanation of this statement in *Dataplex* concerning the extent to which formulators are exempt, EPA reiterated that it has been EPA's longstanding position that the registrant of an end-use product cannot ordinarily add uses that are not on the technical product label and for which there are different data requirements without citing or submitting additional data beyond that supporting the technical registration. *See* Pesticide Registrant Notices 94-1, 98-10, and 95-2. This is consistent with the language of the formulators' exemption, which exempts formulators who purchase a registered technical from the data requirements that pertain to the registered technical. In other words, if the formulator purchases a registered technical or manufacturing use product, the formulator is exempt from the data

requirements that were required of the registered technical or manufacturing use product purchased by the formulator (but only those data requirements). As discussed below, in this case, the formulator is exempt from those data requirements and the issue of data compensation with respect to those data requirements must be resolved between the original data submitter and the technical or manufacturing use product registrant. Thus, the relevant legal issue *Dataplex* resolved was that section 3(c)(2)(D) only exempts the formulator from those data requirements that were required of the registered technical or manufacturing use product purchased by the formulator. It did not address whether data submitters can effectively challenge the compliance status of a registered technical product through a petition to cancel an end-use product that utilizes that technical product as its source of active ingredient.

Bayer also places great significance on EPA's statements in *Dataplex* regarding Congressional intent and that, in certain circumstances, it would be "unreasonable to interpret section 3(c)(2(D) to allow formulators to avoid even paying once...." *Dataplex* at 5. In *Dataplex*, EPA noted that its decision was consistent with one of the rationales supporting the formulators' exemption; namely, that that formulators would pay data compensation to the extent such costs are incorporated into the price of the manufacturing use product. In this context, the Agency opined that nothing in FIFRA suggested that Congress intended formulators to rely on someone else's data without compensation.

A review of the legislative history surrounding adoption of the formulators' exemption indicates that while data compensation was a consideration, the primary purpose of section 3(c)(2)(D)was to simplify the registration of reformulated products, both for the Agency and for formulators. In fact, the legislative history of the 1978 amendments to FIFRA indicates that they were primarily designed to facilitate the implementation of major changes made to FIFRA in 1972 and to improve the operation of the federal pesticide registration program. (H.R. Rep. 95-663, at 1988 and 1990 (1977); S. Rep. 95-334, at 1 (1977)). The largest concern was that "the registration and reregistration process has ground to a virtual halt." (S. Rep. 95-334, at 3). One of the provisions included to improve EPA's ability to reach registration decisions more promptly was the formulators' exemption. The Senate Report described the provision in its section-by-section analysis as:

> "establish[ing] a simplified system for the registration of pesticides, and would exempt applicants who propose to purchase registered technical-grade or manufacturing-use pesticides for formulation into end-use products from submission of data pertaining to the safety of such purchased product, and from the obligation to offer to pay or pay compensation to the person from whom the pesticides was purchased under section 3(c)(1)(D) for use of data relating to the safety of the purchased product."

(S. Rep., 95-334, at 19).[3]

The legislative history shows that the emphasis was on allowing EPA to use a "generic" approach to pesticide registration, and "devote more attention to basic or technical material of these manufactures." (S. Rep. No. 95-334 at 27). The formulators' exemption codified this "generic" approach. In further explanation of the legislation, the House Report provides:

[3] Originally, the data compensation provision was codified at FIFRA section 3(c)(1)(D). Subsequent amendments to FIFRA caused the data compensation provision to be renumbered and it is now be codified at FIFRA section 3(c)(1)(F).

> Currently there is no differentiation in FIFRA between basic manufacturers and formulators. H.R. 8681 would obviate the need for formulators to furnish certain registration data by providing authority for "generic" registration. Formulators who buy registered basic pest control chemicals from another producer to formulate his purchased pesticide into an end-use product would not be required to submit data requirements as to the basic pest control chemical. Under the "generic" registration plan, detailed submission and evaluations of the basic chemical need not be repeated with each formulation. Registration actions would be based on the unique aspects of the particular formulation, applications will be simplified and formulators relieved of the need to offer to pay for the registration data except in the purchase price of the basic pest control chemical.

(H.R. Rep. No. 95-663, at 5). Further insight as to the purpose of the legislation can be found in testimony by the Administrator of EPA:

> As we testified last month, it has become increasingly clear that we are spending far too much time on individual end-use formulation applications, and that the whole structure for registration needs to be focused primarily on the chemicals themselves rather than thousands of individual applications for products containing mixtures of chemicals. Section 1 of our bill would facilitate that restructuring. We envision a system in which it is the technical material which becomes the focal point for registration, with the bulk of the safety data obtained from manufacturing-use, rather than end-use, registration. This would mean that the issues of compensation for the most expensive data—chronic feeding, environmental chemistry, fish and wildlife, and so forth—would be worked out among the registrants of technical products. The cost of that data *could* be included in the price for which the technical product sells. Thus, the formulator, *would in effect* be buying data rights along with the technical material, without having to go through the 3(c)(1)(D) procedures. Formulators might have to engage in 3(c)(1)(D) transactions for data specifically pertaining to the end-use formulation—if that data had been submitted by another formulator, for instance—but such transactions would be relatively simple. In other words, we see two sets of registrants who must settle up with one another: registrants of technical or manufacturing-use materials, and registrants of formulated products. We believe that the Act should specifically advocate this dichotomy and specify that formulators who purchase a registered pesticide product from another product need not submit data pertaining to the safety of the purchased product, as opposed to the safety of the formulated end-use products.

(H. R. Rep. No. 95-343(I) at 11 (1977)) (emphasis added). Thus, from a data compensation perspective, the focus of the formulators' exemption was to create a framework where data compensation "would be worked out among the registrants of technical products" and to protect

the formulator from duplicative payment for data development costs.

In *Dataplex*, however, the formulator was arguing that it was exempt from data requirements that were not the same as data requirements for the technical grade chemical used to formulate the end-use product (because the uses for which the technical product was registered were not the same as the uses for which the company in *Dataplex* was formulating its product). Consequently, there would be no opportunity for the issue of data compensation to be worked out among the original data submitter and the registrant of the technical or manufacturing use product pursuant to section 3(c)(1)(F) of FIFRA. In that case, there would be no market forces at work to pass through costs to the formulator. It was in this context that EPA concluded that it would be unreasonable "to allow formulators to avoid even paying once in certain circumstances." Again, EPA was merely emphasizing that the formulators' exemption only exempts the formulator from data requirements applicable to the registered technical product to the extent that the 3(c)(1)(F) procedures allowed for the original data submitter to be compensated. In other words, it would be unreasonable interpret the formulators' exemption such that it would completely circumvent the protection afforded original data submitters under section 3(c)(1)(F) to seek compensation for data from the registrant selling the technical or manufacturing product to the formulator.

Here, in contrast, the use patterns of the end-use products are not different from those that were purportedly supported by the technical registration. Thus, the predicate condition for the formulators' exemption has been met; namely, the formulator has purchased a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the application, and the uses of the formulated product are not broader than those contemplated by the purchased technical product.[4] To the extent that the data requirements for the registered technical and formulator's end-use product are the same, the formulator is exempt from those data requirements. *See* S. Rep. No. 95-334 at 28. ("Specifically, formulators who purchase registered technical-grade chemicals to incorporate into end-use products would be exempted from data requirements on the technical-grade chemicals.").

The real heart of the issue here is Bayer's contention that Ensystex III did not make an offer to pay for data necessary to support its technical registration. Under the statutory framework established by Congress, to the extent that the data requirements of the reformulated end-use product are the same as the data requirements for the registered technical or manufacturing use registration, the end-use formulator does not need to cite to or provide data that pertaining to those same data requirements. Here, under the statutory framework, Bayer's recourse is limited to seeking data compensation for the data at issue from the technical registrant, not the end-use formulator. The fact that Bayer is time-barred from bringing a petition to cancel the technical registration for failure to make an offer to pay does not change the scope of the formulators' exemption. Bayer cannot now circumvent this bar through a collateral attack on Ensystex IV's end-use registrations by imputing a limitation on the formulators' exemption that is not supported by the text of the exemption or the legislative history. Accordingly, Bayer's petition with respect to Ensystex IV's remaining end-use product registrations as well as Ensystex IV's

[4] Bayer suggests that the rationale behind exempting formulators from 3(c)(1)(D) transactions with respect to generic data—that formulators pay for data through the purchase price of the product it is reformulating, is inapplicable when dealing with closely related companies. Nonetheless, Bayer does not contest that Ensystex III and Ensystex IV are distinct legal entities. Nor does Bayer argue that Ensystex IV is not "another producer" for purposes of the exemption.

"Bithor G" and "Bithor G GC" applications is **DENIED.**[5]

Sincerely,

Lois Rossi

Lois Rossi, Director
Registration Division

cc: Venus Eagle, RD
Andrew J. Simons, OGC

[5] Bayer also asserts that Ensystex IV cannot rely on the formulators' exemption to secure approval of registrations unless "there are available to EPA for its review all data that are necessary to make the required risk/benefit finding under FIFRA section 3(c)(5) or section 3(c)(7)." 40 CFR § 152.85(e). Bayer argues that because Ensystex IV's application does not cite to or contain all the data necessary for registration, EPA does not have available to it data necessary to make the required finding under FIFRA. Not so. It is well established that for purposes of making its risk/benefit determination, EPA is not limited to data cited or provided by the applicant. *See generally*, 49 Fed. Reg. 30884, 901-02 (August 1, 1984) (section 3(c)(1)(D) only applies to information required to be submitted, not for other purposes under FIFRA such as determining the risk benefit consequences of use). Indeed, EPA does not routinely reconsider the data supporting the technical registration each time a new end-use product is registered, just as EPA does not routinely reconsider the data underlying a registered product when a "me-too" application is filed.

Exhibit 3

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 19

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

Charles A. O'Connor, III
Lawrence J. Joseph
McKenna & Cuneo, L.L.P.
1900 K Street, N.W.
Washington, D.C. 20006-1108

Dear Messrs. O'Connor and Joseph:

Thank you for your letter of October 3, 2000, to Mr. Jay Ellenberger and Ms. Michele Knorr of the Agency regarding use of Spray Drift Task Force data and the AgDRIFT model for registration and tolerance actions. In your letter you provide an opinion for use of these data and the model by member and non-member companies for these actions and ask the Agency to respond accordingly with its agreement or disagreement. We have given your letter full consideration and offer our response.

The Agency agrees with key elements of your characterization of the Spray Drift Task Force's (SDTF) spray drift data and of the AgDRIFT model and that EPA may not allow a non-member applicant or registrant to utilize compensable SDTF data to satisfy EPA data requirements unless that applicant or registrant has first offered to pay compensation to the SDTF. Further, EPA agrees that the CRADA in no way alters the SDTF's otherwise applicable compensation rights under FIFRA.

While EPA cannot, in the abstract, assess whether its use of SDTF data and any other data in connection with a specific risk assessment will give rise to compensation obligations, the analysis below provides an explanation of how the Agency would make this determination with regard to spray drift data and other data submitted to support or maintain pesticide registrations.

As provided in 40 CFR Part 152.80.–. 99, and as further explained in the preamble to those regulations at 49 FR 30,884, 30,888 (Aug. 1, 1984), an applicant is obligated to submit or cite all data necessary to satisfy EPA data requirements; applicants are not required to submit or cite all data that EPA may evaluate for the purpose of determining whether the pesticide satisfies the FIFRA unreasonable adverse effects standard or the FFDCA section 408 safety standard. Thus, EPA may utilize spray drift data, including the SDTF's data, in connection with a

registration action where no offer to pay has been made if the applicant has otherwise fully satisfied Agency spray drift data requirements. Accordingly, the critical inquiry in determining whether a given data submitter such as the SDTF is entitled to an offer of compensation is whether an applicant must rely on the submitter's data to satisfy Agency data requirements.

As you know, applicants can satisfy Agency data requirements in one of two ways: (1) By citing all data in the Agency's files (the "cite-all" method); or (2) By demonstrating compliance with each applicable requirement (the "selective method"). When the cite-all method is used, the applicant is relying upon, and offering compensation for, all relevant data in the Agency's files, so the Agency makes no determination as to whether an applicant need have offered compensation for any particular data. An offer having been made, the parties can negotiate a fair price for such data or, failing negotiations, either party may request binding arbitration under the auspices of the Federal Mediation and Conciliation Service to determine the amount and terms of compensation. When an applicant chooses the selective method, however, EPA must determine whether the data cited by the applicant satisfy the Agency's requirements. Agency data requirements are set forth in 40 CFR Part 158, but may also be established through the issuance of data call-ins (DCIs) under FIFRA section 3(c)(2)(B), or may be established on a case-by-case basis at registration, for amended registration, or reregistration (see 40 CFR section 158.75).

In assessing whether a given applicant has satisfied Agency spray drift data requirements, EPA will therefore assess the application against the existing spray drift requirements at 40 CFR section 158.440, determine whether any additional spray drift data have been required for similar products under section 3(c)(2)(B), as well as determine, as provided in section 158.75, whether any data over and above that set forth in the regulation or required by DCI are necessary to support registration. In making the latter determination, EPA will assess whether the applicant's spray drift data submissions and/or citations would be sufficient to allow the Agency to evaluate the drift characteristics of the applicant's product. If indeed the Agency would need to evaluate the results of additional spray drift data to determine the appropriateness of existing use directions and restrictions, the applicant will be required to submit or cite additional spray drift data.

It is important, however, to distinguish those circumstances where data in addition to that submitted or cited by the applicant provide useful or cumulative information, from the circumstance where the additional data are in fact necessary to evaluate adequately the registered or proposed uses of the product. In the former situation, applicants are not required to submit or cite additional data. For example, in determining the appropriate signal word (i.e., danger, warning caution) on a proposed pesticide product label, EPA takes into account not only the acute toxicology studies submitted by an applicant for registration, but also considers the same types of studies submitted by registrants of substantially similar products. Provided the applicant has submitted valid studies that satisfy EPA's acute toxicology data requirements, the applicant is not required to offer compensation to the registrants of the substantially similar

products even though EPA takes that registrant's data into account in determining the appropriate signal word. On the other hand, where the Agency's review of previously submitted data indicate that data submitted or cited by an applicant for registration are invalid or do not provide reliable results for assessing the risks (or benefits, when such information is required to be submitted) of the pesticide, the Agency will require the applicant to submit or cite that additional information.

I hope this letter clarifies the Agency position regarding the requirement for non-member applicants to cite SDTF data. If you have any questions, please call me or Jay Ellenberger at 703/305-7099.

Sincerely,

Marcia E. Mulkey, Director
Office of Pesticide Programs

cc Jay Ellenberger/FEAD
Jim Jones/RD
Elizabeth Leovey/EFED
Lois Rossi/SRRD
Margaret Stasikowski/HED
Mark Dyner/OGC
Donald R. Flint, SDTF Administrative Committee Chairman

Exhibit 4

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 11, 2014

David L. Olson
United Phosphorus
630 Freedom Business Center
Site 402
King of Prussia, PA 19406

Dear Mr. Olson:

Thank you for letter of January 24th regarding the Generic Residential Exposure Task Force's (GRETF's) response to EPA's Pyrethroid Data Call-Is (DCIs).

You are correct that EPA's consideration of data in making a registration review or registration determination does not by itself compel submission or citation of data. EPA must first require those data. When EPA requires such data in connection with either registration or a DCI during registration review, applicants and registrants may choose to cite and offer to pay compensation for previously submitted data that fulfills the requirement, or they may choose to satisfy the data requirement by submitting their own studies that meet agency data requirements. Accordingly, if GRETF members choose to satisfy registration review data needs for the pyrethroids through submission of their own data, and those data meet EPA requirements, GRETF is not required to cite other data submitted, including data generated by the Residential Exposure Joint Venture (REJV), even if EPA uses the REJV data in conducting its risk assessment. However, if the data generated by GRETF do not fully satisfy the data requirements, it may have to cite the REJV to satisfy the requirement.

If you have further questions, feel free to contact Richard Dumas. He can be contacted either by phone at 703-308-8015 or by email at dumas.richard@epa.gov.

Sincerely,

Richard P Keigwin, Jr

Richard P. Keigwin, Director
Pesticide Re-evaluation Division
Office of Pesticide Program
U.S. Environmental Protection Agency
Mail Code 7508P
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Cc: Janelle Kay (Pyxis) (secretary of GRETF)
James P. Rathvon (Paley Rothman) (GRETF Counsel)
Mark Dyner (EPA/Office of General Counsel)

Exhibit 5

Form Approved OMB No. 2070-0060

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

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Ingredient: Glufosinate-ammonium (CAS No. 77182-82-2; Chemical Code: 128850)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC DATA REQUIREMENTS					
830.1550	Product identity and composition	50734401	Ragan and Massey, Inc.	OWN	
830.1600	Description of Materials Used to Produce the Product	50734401	Ragan and Massey, Inc.	OWN	
830.1620	Description of the Production Process	50734401	Ragan and Massey, Inc.	OWN	
830.1650	Description of the Formulation Process				Not applicable[1]
830.1670	Discussion of Formation of Impurities	50734401	Ragan and Massey, Inc.	OWN	
830.1700	Preliminary Analysis	50734402 50734403 50734404	Ragan and Massey, Inc. Ragan and Massey, Inc. Ragan and Massey, Inc.	OWN OWN OWN	
830.1750	Certified Limits	50734401	Ragan and Massey, Inc.	OWN	
830.1800	Enforcement Analytical Method	50734402 50734403 50734404	Ragan and Massey, Inc. Ragan and Massey, Inc. Ragan and Massey, Inc.	OWN OWN OWN	
830.6302	Color	50734405 50734415	Ragan and Massey, Inc. Ragan and Massey, Inc.	OWN OWN	
830.6303	Physical State	50734405 50734415	Ragan and Massey, Inc. Ragan and Massey, Inc.	OWN OWN	
830.6304	Odor	50734405 50734415	Ragan and Massey, Inc. Ragan and Massey, Inc.	OWN OWN	
830.6313	Stability to Normal and Elevated Temperatures, Metals and Metal Ions	50734415	Ragan and Massey, Inc.	OWN	
830.6314	Oxidation/Reduction: Chemical Incompatibility	50734408	Ragan and Massey, Inc.	OWN	

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Ingredient: Glufosinate-ammonium (CAS No. 77182-82-2; Chemical Code: 128850)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6315	Flammability	50734416	Ragan and Massey, Inc.	OWN	Waiver[2]
830.6316	Explodability	50734409	Ragan and Massey, Inc.	OWN	
830.6317	Storage Stability	50734416	Ragan and Massey, Inc.	OWN	PRN 92-5[3]
830.6319	Miscibility	50734416	Ragan and Massey, Inc.	OWN	Not applicable[4]
830.6320	Corrosion Characteristics	50734416	Ragan and Massey, Inc.	OWN	PRN 92-5[3]
830.6321	Dielectric Breakdown Voltage	50734416	Ragan and Massey, Inc.	OWN	Not required[5]
830.7000	pH	50734405 50734415	Ragan and Massey, Inc. Ragan and Massey, Inc.	OWN OWN	
830.7050	UV/Visible Absorption	50734405 50734415	Ragan and Massey, Inc. Ragan and Massey, Inc.	OWN OWN	
830.7100	Viscosity	50734416	Ragan and Massey, Inc.	OWN	Not applicable[6]
830.7200	Melting Point/Melting Range	50734405 50734415	Ragan and Massey, Inc. Ragan and Massey, Inc.	OWN OWN	
830.7220	Boiling Point/Boiling Range	50734416	Ragan and Massey, Inc.	OWN	Not applicable[7]
830.7300	Density/Relative Density/Bulk Density	50734405 50734415	Ragan and Massey, Inc. Ragan and Massey, Inc.	OWN OWN	
830.7370	Dissociation Constants in Water	50734413	Ragan and Massey, Inc.	OWN	
830.7520	Particle size, fiber length, and diameter distribution	50734416	Ragan and Massey, Inc.	OWN	Waiver[8]
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	50734415	Ragan and Massey, Inc.	OWN	
830.7560	Partition Coefficient (n-octanol/water), Generator Method				See 830.7550

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Ingredient: Glufosinate-ammonium (CAS No. 77182-82-2; Chemical Code: 128850)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method, Shake Flask Method	50734415	Ragan and Massey, Inc.	OWN	
830.7860	Water Solubility: Generator Column Method				See 830.7840
830.7950	Vapor Pressure	50734415	Ragan and Massey, Inc.	OWN	
870.1100	Acute oral toxicity – rat	00142430 00142431 00142432		OLD OLD OLD	See endnote[9]
870.1200	Acute dermal toxicity – rat	00142436 00142437		OLD OLD	See endnote[10]
870.1300	Acute inhalation toxicity – rat	00151496 00151497		OLD OLD	See endnote[11]
870.2400	Eye irritation	00142438		OLD	See endnote[12]
870.2500	Skin irritation	00142438		OLD	See endnote[13]
870.2600	Skin sensitization	00142439		OLD	See endnote[14]
GENERIC DATA REQUIREMENTS					
850.2100	Acute Avian Oral Toxicity	00142450 00142451		OLD OLD	See endnote[15]

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Ingredient: Glufosinate-ammonium (CAS No. 77182-82-2; Chemical Code: 128850)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.2200	Acute Avian Dietary Toxicity	00150988 00150989		OLD OLD	See endnote[16]
850.2400	Wild Mammal Toxicity				See 870 series
850.2300	Avian Reproductive Toxicity	40345649 40345650		OLD OLD	See endnote[17]
850.2500	Simulated or Actual Field Testing				Not required
850.1075	Freshwater Fish Toxicity	00142454 00142455 00144338 00159913 00159914		OLD OLD OLD OLD OLD	See endnote[18]
850.1010	Freshwater Invertebrate Toxicity	00142456 00159915 00144339 00145067		OLD OLD OLD OLD	See endnote[19]
850.1025, 850.1035, 850.1045, 850.1055, 850.1075	Acute Toxicity Estuarine and Marine Organisms	41396104 41396105 41396107 41396108 41396109 41396110 42262403		OLD OLD OLD OLD OLD OLD OLD	See endnote[20]

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Ingredient: Glufosinate-ammonium (CAS No. 77182-82-2; Chemical Code: 128850)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.1300	Aquatic Invertebrate Life Cycle (Freshwater)	40501010		OLD	See endnote[21]
850.1350	Aquatic Invertebrate Life Cycle (Saltwater)				Not required[22]
850.1400	Fish Early Life Stage (Freshwater)				Not required[23]
850.1400	Fish Early Life Stage (Saltwater)				Not required[24]
850.1500	Life Cycle Fish				Not required[25]
850.1710, 850.1730, 850.1850	Aquatic Organisms Bioavailability, Biomagnification, Toxicity	40501017 41323130		OLD OLD	See endnote[26]
850.1950	Simulated or Actual Field Testing for Aquatic Organisms				Not required
850.1735	Whole Sediment: Acute Freshwater Invertebrates				Not required
850.1740	Whole Sediment: Acute Marine Invertebrates				Not required
N/A	Whole Sediment: Chronic Invertebrate Freshwater and Marine				Not required
850.3020	Honey Bee Acute Contact Toxicity	40345654 41364002		OLD OLD	See endnote[27]
850.3030	Honeybee Toxicity of Residues on Foliage				Not required
850.3040	Field Testing for Pollinators				Not required
870.6100	Delayed Neurotoxicity (Acute) – Hen				Not required

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.6200	Acute Neurotoxicity – Rat	45190701 45190702 45190703 45190704		OLD OLD OLD OLD	See endnote[28]
870.3100	90-Day Oral: Rodent	40345609 44076201 44076202 44076203 44076206 44076207 44068501 45179103		OLD OLD OLD OLD OLD OLD OLD OLD	See endnote[29]
870.3150	90-Day Oral: Non-Rodent	40345608 44068502		OLD OLD	See endnote[30]
870.3200	21/28-Day Dermal Toxicity	40345605		OLD	See endnote[31]
870.3250	90-Day Dermal Toxicity				Not required
870.3465	90-Day Inhalation Toxicity	40345606 47058101	 Bayer CropScience LP	OLD PAY	See endnote[32]
870.6100	28-Day Delayed Neurotoxicity Hen				Not required
870.6200	90-Day Neurotoxicity	45179101 45179102 45297001		OLD OLD OLD	See endnote[33]

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.4100	Chronic Oral Rodent	40345607 41144701 44539501		OLD OLD OLD	See endnote[34]
870.4200	Carcinogenicity	40345607 40345609 41144701 41144702 44539501		OLD OLD OLD OLD OLD	See endnote[35]
870.3700	Reproduction/Developmental Toxicity Screening Test	00142445 00142446 00151499 00151500 40345610 40345611 41144703 43829405 44076204 44076205 44076209		OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD OLD	See endnote[36]
870.3800	2-Generation Reproduction: Rat	40345612		OLD	See endnote[37]
870.6300	Developmental Neurotoxicity Study	46455701	Bayer CropScience LP	PAY	See endnote[38]

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.5100	Bacterial Reverse Mutation Test	00142440 (AC072962)		OLD	See endnote[39]
870.5300, 870.5375	*In vitro* Mammalian Cell Assay	40345616		OLD	See endnote[40]
870.5385, 870.5395, 870.5450, 870.5550	*In vivo* Cytogenetics and Other Effects	00142441 (AC072962) 40345614 41144704		OLD OLD OLD	See endnote[41]
870.7485	Metabolism and Pharmacokinetics	40345640 40345642 43766913 43766914 43778402		OLD OLD OLD OLD OLD	See endnote[42]
870.7200	Companion Animal Safety				Not required
870.7600	Dermal Penetration	40345620 45922103		OLD OLD	See endnote[43]
870.7800	Immunotoxicity	48491101	Bayer CropScience LP	PAY	See endnote[44]
875.1100	Dermal Exposure – Outdoor		PHED	PL	See endnote[45]
875.1200	Dermal Exposure - Indoor				Not required
875.1300	Inhalation Exposure – Outdoor		PHED	PL	See endnote[45]
875.1400	Inhalation Exposure - Indoor				Not required
875.1500	Biological Monitoring		PHED	PL	See endnote[45]

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.1600	Data Reporting and Calculations		PHED	PL	See endnote[45]
875.1700	Product Use Information		PHED	PL	See endnote[45]
875.2100	Dislodgeable Foliar Residue and Turf Transferable Residues	45251401		OLD	
875.2200	Soil Residue Dissipation	44972201		OLD	
		44972202		OLD	
		44972203		OLD	
		44972204		OLD	
		44972205		OLD	
		44972206		OLD	
		44972207		OLD	
		44983501		OLD	
		45262901		OLD	
		45262902		OLD	
		45663701		OLD	
		45663702		OLD	
		45663703		OLD	
		46042401		OLD	
		46042402		OLD	
875.2400	Dermal Exposure				See 875.2200
875.2500	Inhalation Exposure				See 875.2200

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
875.2600	Biological Monitoring				See 875.2200
875.2700	Product Use Information				See 875.2200
875.2800	Descriptions of Human Activity				See 875.2200
875.2900	Data Reporting and Calculations				See 875.2200
875.3000	Nondietary Ingestion Exposure				See 875.2200

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201-1	Droplet Size Spectrum	42565901		OLD	
		42608401		OLD	
		42907401		OLD	
		43254001		OLD	
		43485601		OLD	
		43485602		OLD	
		43485603		OLD	
		43485604		OLD	
		43493801		OLD	
		43493802		OLD	
		43508001		OLD	
		43535801		OLD	
		43535802		OLD	
		43657601		OLD	
		43657602		OLD	
		43665401		OLD	
		43665402		OLD	
		43757801		OLD	
		43757802		OLD	
		43766501		OLD	
		43766502		OLD	
		43766503		OLD	
		43766504		OLD	

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201-1	Droplet Size Spectrum (cont.)	43781101		OLD	
		43803501		OLD	
		43832101		OLD	
		43832102		OLD	
		43845501		OLD	
		43845901		OLD	
		43925701		OLD	
		43953001		OLD	
		43953002		OLD	
		44010201		OLD	
		44070001		OLD	
		44100901		OLD	
		44134101		OLD	
		44178701		OLD	
		44310401		OLD	
		44640801		OLD	
		44640901		OLD	
		44641001		OLD	
		44696901		OLD	
		44747401		OLD	
		44763001		OLD	
		44878601		OLD	
		44908901		OLD	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
201-1	Droplet Size Spectrum (cont.)	45536001		OLD	
202-1	Droplet Size Spectrum				See 201-1
850.4100	Tier 1: Seedling Emergence	41396111		OLD	See endnote[46]
		48531301	Bayer CropScience LP	PAY	
		48718501	Bayer CropScience LP	PAY	
850.4150	Tier 1: Vegetative Vigor	41396112		OLD	See endnote[47]
		41396113		OLD	
		47542602	Bayer CropScience LP	PAY	
850.4400, 850.4500	Tier 1: Aquatic Plant Growth	40345653		OLD	See endnote[48]
		42262404		OLD	
		47542603	Bayer CropScience LP	PAY	
		48444816	Bayer CropScience LP	PAY	
		48444817	Bayer CropScience LP	PAY	
850.4100	Tier 2: Seedling Emergence	41396111		OLD	See endnote[49]
		48531301	Bayer CropScience LP	PAY	
		48718501	Bayer CropScience LP	PAY	
850.4150	Tier 2: Vegetative Vigor	41396112		OLD	See endnote[50]
		41396113		OLD	
		47542602	Bayer CropScience LP	PAY	

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Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
850.4400, 850.4500	Tier 2: Aquatic Plant Growth	40345653		OLD	See endnote[51]
		42262404		OLD	
		47542603	Bayer CropScience LP	PAY	
		48444816	Bayer CropScience LP	PAY	
		48444817	Bayer CropScience LP	PAY	
850.4300	Terrestrial Field				Not required
850.4450	Aquatic Field				Not required
850.4025	Target Area Phytotoxicity				Not required
835.2120	Hydrolysis	40345656		OLD	See endnote[52]
835.2240	Photodegradation in Water	40345657		OLD	See endnote[53]
		41323115		OLD	
835.2410	Photodegradation in Soil	40345658		OLD	See endnote[54]
		41920102		OLD	
835.2370	Photodegradation in Air				Not required
835.4100	Aerobic Soil Metabolism	40345659		OLD	See endnote[55]
		41323118		OLD	
		41323119		OLD	
		41920103		OLD	

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835.4200	Anaerobic Soil Metabolism	40501014 41323119 41323120 41920103		OLD OLD OLD OLD	See endnote[56]
835.4300	Aerobic Aquatic Metabolism	40345660 45204401 45204402		OLD OLD OLD	See endnote[57]
835.4400	Anaerobic Aquatic Metabolism	46258601	Bayer CropScience LP	PAY	See endnote[58]
835.1230, 835.1240	Leaching/Adsorption/Desorption	40345662 41323121		OLD OLD	See endnote[59]
835.1410	Volatility – Laboratory	41323122 41920104		OLD OLD	See endnote[60]
835.8100	Volatility – Field				Not required
835.6100	Soil Field Dissipation Study	40345663 40345664 40345665 41323124 43110402 43766915 43766916		OLD OLD OLD OLD OLD OLD OLD	See endnote[61]
835.6200	Aquatic Sediment Field Dissipation Study				Not required[62]

Signature	Name and Title	Date
	Ann M. Tillman, PhD | Agent	Jan. 30, 2019

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

DATA MATRIX

Date Jan. 30, 2019	EPA Reg No./File Symbol 84009-	Page 16 of 19
Applicant's/Registrant's Name & Address Ragan and Massey, Inc. 101 Ponchatoula Parkway Ponchatoula , LA 70454	Product RM Glufosinate-Ammonium Technical	

Ingredient: Glufosinate-ammonium (CAS No. 77182-82-2; Chemical Code: 128850)

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
835.6300	Forest Field Dissipation Study				Not required
835.6400	Combination and Tank Mixes				Not required
835.7100	Ground Water Monitoring				Not required
850.6100	Environmental Chemistry Methods	40345666		OLD	See endnote[63]
		41323123		OLD	
		41920106		OLD	
		43766915		OLD	
		47542606	Bayer CropScience LP	PAY	
		47542607	Bayer CropScience LP	PAY	
		49055301	Bayer CropScience LP	PAY	

Signature	Name and Title	Date
	Ann M. Tillman, PhD | Agent	Jan. 30, 2019

Endnotes for Data Matrix for RM Glufosinate-Ammonium Technical

[1] **830.1650 –** These data are not required for registration of a technical product. See 830.1620.

[2] **830.6315 -** Ragan and Massey, Inc. requests a waiver from the requirement of this data requirement since RM Glufosinate-Ammonium Technical is a solid and does not contain flammable components. Please refer to the Confidential Statement of Formula for RM Glufosinate-Ammonium Technical.

[3] **830.6317, 830.6320 -** Per PR Notice 92-5, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Ragan and Massey, Inc. will submit these data if required as a condition of registration.

[4] **830.6319 -** This data requirement is required when the product is an end use product and an emulsifiable liquid to be diluted with petroleum solvents. RM Glufosinate-Ammonium Technical is not an end-use product to be diluted with petroleum solvents prior to application. Therefore, these data are not applicable to RM Glufosinate-Ammonium Technical.

[5] **830.6321 -** These data are not required for registration of a technical product and are not applicable to RM Glufosinate-Ammonium Technical.

[6] **830.7100 -** These data are required when the product is a liquid. RM Glufosinate-Ammonium Technical is a solid and these data are not required.

[7] **830.7220 -** This guideline is not applicable to solid products.

[8] **830.7520 -** Ragan and Massey, Inc. is seeking a waiver for this data requirement for RM Glufosinate-Ammonium Technical because the product is not water insoluble and it is not a fibrous material.

[9] **870.1100** – The studies cited are acceptable and satisfy the data requirement as per the July 25, 2012 Glufosinate Ammonium - Updated Human Health Risk Assessment for the Proposed New Use of Glufosinate Ammonium in/on Citrus Fruit (Crop Group 10), Pome Fruit (Crop Group 11), Stone Fruit (Crop Group 12), Olives and Sweet Corn (DP Barcode D387413) (Human Health RA).

[10] **870.1200** – The studies cited are acceptable and satisfy the data requirement as per the Human Health RA.

[11] **870.1300** – The studies cited are acceptable and satisfy the data requirement as per the Human Health RA.

[12] **870.2400** – The study cited is acceptable and satisfies the data requirement as per the Human Health RA.

[13] **870.2500** – The study cited is acceptable and satisfies the data requirement as per the Human Health RA.

[14] **870.2600** – The study cited is acceptable and satisfies the data requirement as per the Human Health RA.

[15] **850.2100** – The studies cited are acceptable and satisfy the data requirement as per the Sept. 12, 2014 Environmental Fate and Ecological Risk Assessment for the Registration Review of Glufosinate (EFED RA). Passerine data have not been submitted and these data were not required in the Registration Review DCI.

[16] **850.2200** – The studies cited are acceptable and satisfy the data requirement as per the EFED RA.

[17] **850.2300** – The studies cited are acceptable and satisfy the data requirement as per the EFED RA. Newly submitted data that are duplicative of previously submitted data are not cited.

[18] **850.1075** – The studies cited are acceptable or supplemental but satisfy the data requirement as per the EFED RA. Newly submitted data that are duplicative of previously submitted data are not cited.

[19] **850.1010** – The studies cited are acceptable or supplemental but satisfy the data requirement as per the EFED RA. Newly submitted data that are duplicative of previously submitted data are not cited.

[20] **850.1025, 850.1035, 850.1045, 850.1055, 850.1075** – The studies cited are acceptable or supplemental but satisfy the data requirement as per the EFED RA.

Endnotes for Data Matrix for RM Glufosinate-Ammonium Technical

[21] **850.1300** – The study cited is acceptable and satisfies the data requirement as per the EFED RA. Newly submitted data that are duplicative of previously submitted data are not cited.

[22] **850.1350** – These data have not been submitted nor are required for Registration Review as per the EFED RA.

[23] **850.1400** – These data have not been submitted nor are required for Registration Review as per the EFED RA.

[24] **850.1400** – These data have not been submitted nor are required for Registration Review as per the EFED RA.

[25] **850.1500** – These data have not been submitted nor are required for Registration Review as per the EFED RA.

[26] **850.1710, 850.1730, 850.1850** – The studies cited are acceptable or supplemental but satisfy the data requirement as per the EFED RA.

[27] **850.3020** – The studies cited are acceptable or supplemental but satisfy the data requirement as per the EFED RA.

[28] **870.6200** – The studies cited are acceptable and satisfy the data requirement as per the Human Health RA.

[29] **870.3100** – The studies cited are acceptable and satisfy the data requirement as per the Human Health RA.

[30] **870.3150** – The studies cited are acceptable and satisfy the data requirement as per the Human Health RA.

[31] **870.3200** – The study cited is acceptable and satisfies the data requirement as per the Human Health RA.

[32] **870.3465** – The studies cited are acceptable or supplemental but satisfy the data requirement as per the Human Health RA.

[33] **870.6200** – The studies cited are acceptable and satisfy the data requirement as per the Human Health RA. Unacceptable data are not cited.

[34] **870.4100** – The studies cited are acceptable or supplemental but satisfy the data requirement as per the Human Health RA. Chronic dog data are not cited as these data are no longer required per the 2007 revisions to 40 CFR Part 158.

[35] **870.4200** – The studies cited are acceptable and satisfy the data requirement as per the Human Health RA.

[36] **870.3700** – The studies cited are acceptable and satisfy the data requirement as per the Human Health RA. Unacceptable data are not cited.

[37] **870.3800** – The study cited is acceptable and satisfies the data requirement as per the Human Health RA.

[38] **870.6300** – The study cited is acceptable and satisfies the data requirement as per the Human Health RA.

[39] **870.5100** – The study cited is acceptable and satisfies the data requirement as per the Human Health RA.

[40] **870.5300, 830.5375** – The study cited is acceptable and satisfies the data requirement as per the Human Health RA. Note: the incorrect MRID number was listed in the Human Health RA; the correct MRID number is cited.

[41] **870.5385, 870.5395, 870.5450, 870.5550** – The studies cited are acceptable and satisfy the data requirement as per the Human Health RA.

Endnotes for Data Matrix for RM Glufosinate-Ammonium Technical

[42] **870.7485** – The studies cited are acceptable and satisfy the data requirement as per the Human Health RA.

[43] **870.7600** – The studies cited are acceptable and satisfy the data requirement as per the Human Health RA.

[44] **870.7800** – The study cited is acceptable and satisfies the data requirement as per the Human Health RA.

[45] **875.1100, 875.1300, 875.1500, 875.1600, 875.1700** – PHED data were used to determine Short/Intermediate Term Agricultural Handler Exposure and Risk Estimates for Glufosinate Ammonium (Spot/Directed Spray Applications) in the Human Health RA.

[46] **850.4100** – The studies cited are supplemental but appear to satisfy the data requirement as per the EFED RA.

[47] **850.4150** – The studies cited are supplemental but appear to satisfy the data requirement as per the EFED RA.

[48] **850.4400, 850.4500** – The studies cited are acceptable or supplemental but appear to satisfy the data requirement as per the EFED RA. Additional data that were submitted, but not required, are not cited.

[49] **850.4100** – The studies cited are supplemental but appear to satisfy the data requirement as per the EFED RA.

[50] **850.4150** – The studies cited are supplemental but appear to satisfy the data requirement as per the EFED RA.

[51] **850.4400, 850.4500** – The studies cited are acceptable or supplemental but appear to satisfy the data requirement as per the EFED RA. Additional data that were submitted, but not required, are not cited.

[52] **835.2120** – The study cited is acceptable and satisfies the data requirement as per the EFED RA.

[53] **835.2240** – The studies cited are acceptable or supplemental but satisfy the data requirement as per the EFED RA.

[54] **835.2410** – The studies cited are acceptable or supplemental but satisfy the data requirement as per the EFED RA; unacceptable data are not cited.

[55] **835.4100** – The studies cited are acceptable or supplemental but satisfy the data requirement as per the EFED RA; unacceptable data are not cited.

[56] **835.4200** – The studies cited are acceptable or supplemental but satisfy the data requirement as per the EFED RA.

[57] **835.4300** – The studies cited are acceptable or supplemental but satisfy the data requirement as per the EFED RA.

[58] **835.4400** – The study cited is supplemental but satisfies the data requirement as per the EFED RA; unacceptable data are not cited.

[59] **835.1230, 835.1240** – The studies cited are acceptable or supplemental but satisfy the data requirement as per the EFED RA; unacceptable data are not cited.

[60] **835.1410** – The studies cited are acceptable and satisfy the data requirement as per the EFED RA.

[61] **835.6100** – The studies cited are acceptable or supplemental but satisfy the data requirement as per the EFED RA; unacceptable or upgradeable data are not cited.

[62] **835.6200** – These data are not required based on the uses proposed to be registered.

[63] **850.6100** – The studies cited, as well as MRID 49055301, appear to satisfy the data requirement as per the EFED RA.

Exhibit 6

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

NOTICE OF PESTICIDE:
_X_ Registration
___ Reregistration
(under FIFRA, as amended)

EPA Reg. Number:	**Date of Issuance:**
84009-34	2/11/20

Term of Issuance:
Unconditional

Name of Pesticide Product:
RM Glufosinate-Ammonium Technical

Name and Address of Registrant (include ZIP Code):

Ragan and Massey, Inc.
c/o Pyxis Regulatory Consulting Inc.
4110 136th St. Ct. NW
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.

2. Make the following label changes before you release the product for shipment:

   - Revise the EPA Registration Number to read, “EPA Reg. No. 84009-34.”

   Submit one copy of the revised final printed label for the record before you release the product for shipment.

Signature of Approving Official:	**Date:**
Erik Kraft, Product Manager 24 Fungicide Herbicide Branch, Registration Division (7505P)	2/11/20

EPA Form 8570-6

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 01/03/2019
- Alternate CSF 1 dated 01/03/2019
- Alternate CSF 2 dated 01/03/2019

If you have any questions, please contact BeWanda Alexander by phone at (703)347-0313, or via email at alexander.bewanda@epa.gov.

Enclosure

RM Glufosinate-Ammonium Technical

ACTIVE INGREDIENT:	**By Wt.**
Glufosinate-ammonium	95.1%
OTHER INGREDIENTS:	4.9%
TOTAL	100.0%

KEEP OUT OF REACH OF CHILDREN

CAUTION

FIRST AID	
If on skin or clothing:	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15 to 20 minutes. • Call a poison control center or doctor for treatment advice.
If inhaled:	• Move person to fresh air. • If person is not breathing, call 911 or ambulance, then give artificial respiration, preferably mouth-to-mouth if possible. • Call a poison control center or doctor for further treatment advice.
If swallowed:	• Call a poison control center or doctor immediately for treatment advice. Have a person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
If in eyes:	• Hold eye open and rinse slowly and gently with water for 15 to 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for further treatment advice.
HOTLINE NUMBER Have the product container or label with you when calling a Poison Control Center or doctor, or when going for treatment. For non-emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378, Monday through Friday, 8:00 AM to 12:00 PM Pacific Time (NPIC Web site: www.npic.orst.edu).	
NOTE TO PHYSICIAN: Glufosinate-ammonium is a glutamine synthetase inhibitor and can interfere with neurotransmitter function. Symptoms may be delayed by up to 48 hours following ingestion. There is no specific antidote. If ingested, endotracheal intubation and gastric lavage should be performed as soon as possible, followed by charcoal and sodium sulfate administration.	

For Chemical Spill, Leak, Fire, or Exposure, call CHEMTREC 1-800-424-9300

Manufactured for:
Ragan & Massey, Inc.
101 Ponchatoula Parkway
Ponchatoula, LA 70454

EPA Reg. No. 84009-
EPA Est. No.
Net Weight: lbs (kg)
Lot No.: See container

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS
CAUTION

Harmful if absorbed through skin. Harmful if inhaled. Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Avoid breathing dust. Wash thoroughly after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove contaminated clothing and wash clothing before reuse.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the Environmental Protection Agency.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.
Do not use this product until you have read the entire label. This manufacturing-use product may be used only for formulation into a herbicide for: Weed control of emerged weeds in noncrop areas, control of weeds and grasses in residential and industrial areas, uses for which the U.S. EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration and uses for experimental purposes that are in compliance with U.S. EPA requirements. This product may be used to formulate products for specific use(s) not listed on this label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such use(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage, disposal or cleaning of equipment.
PESTICIDE STORAGE: Store in original container and keep closed. Store in a cool, dry place.
PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.
CONTAINER HANDLING: Fiber Sacks including Flexible Intermediate Bulk Containers (FIBC) or Fiber Drums With Liners: Nonrefillable container. Do not reuse or refill this container. Completely empty fiber sack or drum liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application or manufacturing equipment. Then offer for recycling if available or dispose of empty fiber sack or fiber drum and liner in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances.

WARRANTY AND LIMITATION OF DAMAGES

Ragan and Massey, Inc. warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes set forth in the complete Directions For Use label booklet ("Directions") when used in accordance with those Directions under the conditions described therein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein. Buyer and all users shall promptly notify this Company of any claims whether based in contract, negligence, strict liability, other tort or otherwise. Upon opening and using this product, buyer and all users are deemed to have accepted the terms of this Warranty and Limitation of Damages which may not be varied by any verbal or written agreement. If terms are not acceptable, return at once unopened.

[EPA approval date]

ACCEPTED
02/11/2020
Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 84009-34